



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0493]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0688. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded--(OMB Control Number 0910-0688)--  
Extension

In the Federal Register of January 23, 2002 (67 FR 3060), we established regulations in § 330.14 (21 CFR 330.14) providing additional criteria and procedures for classifying over-the-counter (OTC) drugs as generally recognized as safe and effective and not misbranded (2002 time and extent application (TEA) final rule). These regulations state that OTC drug products introduced into the U.S. market after the OTC drug review began and OTC drug products without any marketing experience in the United States can be evaluated under the monograph process if the conditions (e.g., active ingredients) meet certain "time and extent" criteria outlined in § 330.14(b). The regulations allow a TEA to be submitted to us by any party for our consideration to include new conditions in the OTC drug monograph system. TEAs must provide evidence described in § 330.14(c) demonstrating that the condition is eligible for inclusion in the monograph system. (Section 330.14(d) specifies the number of copies and address for submission of a TEA.) If a condition is found eligible, any interested parties can submit safety and effectiveness information as explained in § 330.14(f). Safety and effectiveness data includes the data and information listed in 21 CFR 330.10(a)(2), a listing of all serious adverse drug experiences that may have occurred, and an official or proposed compendial monograph. We

published the Guidance for Industry "Time and Extent Applications for Nonprescription Drug Products" on September 29, 2011 (76 FR 60504).

In the Federal Register of October 8, 2010 (75 FR 62404), we published a 60-day notice requesting public comment on the proposed collection of information. In that notice, we stated that based on the number of submissions we had received in the 8 years following publication of the TEA final rule, we expected to receive an average of two TEAs and two submissions of safety and effectiveness data each year. In the same document, we stated in our estimate that approximately 1,525 hours are required to prepare a TEA and approximately 2,350 hours to prepare a safety and effectiveness submission. This estimate is based on a comment from a manufacturer that filed two TEAs that was submitted to the Agency in response to the 60-day notice requesting public comment on this proposed collection of information in the Federal Register of October 8, 2010. The commenter included, as part of the estimated burden of safety and effectiveness data submission, an estimated burden to submit environmental data to conduct an environmental assessment as required by the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 et seq.) (see 21 CFR 25.1), or the application of any categorical exclusion that may be warranted (21 CFR 25.20(f)). Because the information provided in the submission is based on actual experience by a TEA applicant and included an estimated burden to comply with NEPA, we agreed with the submission and adjusted our estimates accordingly. Based on our experience since the October 2010 notice, we continue to estimate that we will receive two TEAs and two safety and effectiveness submissions each year, and that it will take approximately 1,525 hours to prepare a TEA and 2,350 hours to prepare a comprehensive safety and effectiveness submission, to include environmental data.

In the Federal Register of March 24, 2014 (79 FR 16007), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
330.14(c)--Time and Extent Application and (d) <sup>2</sup> --Submission of Information; Confidentiality	2	1	2	1,525	3,050
330.14(f)--Request for Data and Views and (i) <sup>3</sup> --Compendial Monograph	2	1	2	2,350	4,700
Total					7,750

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> TEA.

<sup>3</sup> Safety and effectiveness submission, including environmental data in accordance with 21 CFR 25.1.

Dated: June 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.